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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,276	12/28/2006	Gea Speelmans	0470-061182	9708
28389 7590 02/24/2011 THE WEBB LAW FIRM, P.C. 700 KOPPERS BUILDING 436 SEVENTH AVENUE PITTSBURGH, PA 15219				
EXAMINER				
PURDY, KYLE A				
ART UNIT		PAPER NUMBER		
1611				
MAIL DATE		DELIVERY MODE		
02/24/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/576,276

**Applicant(s)**

SPEELMANS ET AL.

**Examiner**

Kyle Purdy

**Art Unit**

1611

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-37 is/are pending in the application.
- 4a) Of the above claim(s) 24 and 31-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-23 and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4 pages (9/25/08)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

#### **Election Acknowledged**

1. Applicant's election with traverse of the invention of Group I encompassing claims 19-30 in the reply filed on 12/16/2010 is acknowledged. The traversal is on the ground(s) that Cavaliere does not suggest Applicants claimed invention of a composition comprising at least two non-digestible carbohydrates in combination with Bifidobacterium breve. Applicant's position is not found persuasive for the reasons discussed below under 35 USC 103.

2. The requirement is still deemed proper and is therefore made FINAL.

#### **Status of Application**

3. Claims 19-37 are pending, claims 24 and 31-37 are withdrawn as directed to nonelected species and/or invention and claims 19-23 and 25-30 are presented for examination on the merits. The following rejections are made.

#### **Priority**

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It's noted that for the dates to be effective in the case of an intervening reference, an English translation will need to be provided.

#### **Claim Rejections - 35 USC § 103**

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**8. Claims 19-23 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavaliere Vesely et al. (US 5895648; published 04/20/1999, of record).**

9. Cavaliere is directed to feed compositions comprising a mixture of lyophilized live lactic bacteria and one or more oligosaccharides (see abstract). Exemplified bacteria include *Bifidobacterium breve* in a concentration of at least  $50 \times 10^9$  CFU/g, more preferably 100 to  $150 \times 10^9$  CFU/g (see column 3, lines 15-20). The composition is to also consist of one or more

oligosaccharides such as galacto-oligosaccharides and inulin (see column 4, lines 50-60). The composition may further comprise a sugar as well as milk proteins (see column 5, lines 30-65).

10. Cavaliere fails to teach a composition wherein two non-digestible soluble carbohydrates are present together wherein one of the carbohydrates is present in an amount of between 5-95% by weight of the sum of the insoluble carbohydrate components.

11. Regardless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Cavaliere with a reasonable expectation for success in arriving at a composition comprising *Bifidobacterium breve* in an amount of between  $1 \times 10^5$  to  $1.5 \times 10^{11}$  CFU/g together with a mixture of two nondigestible carbohydrates such as galacto-oligosaccharides and inulin (fructopolysaccharide). While Cavaliere fails to teach a composition comprising two indigestible carbohydrates, Cavaliere suggests that the composition comprise "one or more" non-digestible carbohydrates. Thus, any ordinary person would envisage using more than one non-digestible carbohydrate such as galacto-oligosaccharides and inulin with a reasonable expectation for success in providing a prebiotic benefit to the user thereof. With respect to the amount of each non-digestible carbohydrate, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Moreover, if one were to combine both of the obvious non-digestible carbohydrates into a prebiotic composition, one would have been motivated to identify an optimum ratio between the two since the amount of the non-digestible carbohydrate is a result-effective variable, i.e. a variable which achieves a recognized result. Thus, the determination of the optimum or workable ranges of said variable (i.e. improved prebiotic benefit) might be characterized through routine experimentation. See

MPEP 2144.05. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/  
Examiner, Art Unit 1611  
February 22, 2011

**/Sharmila Gollamudi Landau/  
Supervisory Patent Examiner, Art Unit 1611**